THE HONORABLE JOHN C. COUGHENOUR

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

DAVID DEARINGER and GANNA DEARINGER,

Plaintiffs,

v.

ELI LILLY AND COMPANY ,

Defendant.

CASE NO. C21-0060-JCC

ORDER

This matter comes before the Court on Defendant Eli Lilly and Company's second motion for summary judgment (Dkt. No. 86) and Plaintiffs' motion for reconsideration (Dkt. No. 87). Having thoroughly considered the briefing and the relevant record, and finding oral argument unnecessary, the Court hereby GRANTS Defendant's motion (Dkt. No. 86), DENIES Plaintiffs' motion (Dkt. No. 87), and DISMISSES Plaintiffs' Second Amended Complaint ("SAC") (Dkt. No. 37) with prejudice for the reasons explained below.

I. BACKGROUND

In 2018, Plaintiff David Dearinger suffered an intracranial brain hemorrhage, *i.e.*, a stroke, resulting in the permanent loss of "sensory and motor function of the left side of his body." (Dkt. No. 37 at 2–3.) The SAC states that Defendant's prescription erectile dysfunction

drug Cialis was the cause. (*Id.*) Accordingly, it asserts Washington's Product Liability Act ("WPLA") claims, along with fraudulent concealment and loss of consortium. (*See generally id.*)

On December 18, 2023, the Court granted in part Defendant's motion for summary judgment, dismissing Plaintiffs' failure-to-warn claim (Counts 2 and 3) and fraudulent concealment claim (Count 4). (Dkt. No. 84.) However, summary judgment was denied on Plaintiffs WPLA design defect claim (Count 1) and loss of consortium claim (Count 5). (*Id.*) Defendant now moves for summary judgment on those claims. (Dkt. No. 86.) Separately, Plaintiff moves to amend the Court's order (Dkt. No. 84) dismissing the failure to warn and fraudulent concealment claims. (Dkt. No. 87.)

II. DISCUSSION

A. Motion for Summary Judgment

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In making such a determination, the Court must view the facts in the light most favorable to the nonmoving party and draw justifiable inferences in that party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). Ultimately, summary judgment is appropriate against a party who "fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

B. Federal Preemption

Defendant argues that Plaintiffs' design defect claim is preempted because federal law forbids Defendant from changing Cialis's label design without prior Food and Drug Administration ("FDA") approval. (Dkt. No. 86 at 12.) FDA regulations provide that once a drug, whether generic or brand-name, is approved, the manufacturer is prohibited from making any major changes to the "qualitative or quantitative formulation of the drug product, including inactive ingredients, or in the specifications provided in the approved application." 21 C.F.R.

§ 314.70(b)(2)(i).[1] Federal regulation defines three classes of changes: "major changes," "moderate changes," and "minor changes." 21 C.F.R. § 314.70(b)–(d). Major changes "include, but are not limited to[,] . . . changes in the qualitative or quantitative *formulation* of the drug product." *Id.* § 314.70(b)(2)(i) (emphasis added.)

Here, it is uncontroverted that Cialis is an FDA-approved prescription medication which, under federal law, Defendant is prohibited from altering its formulation without prior FDA approval. Based on the plain meaning of the regulation, Defendant could not alter the medication without submission to the FDA for "approval *prior* to distribution of the product made using the change." *See id.* (emphasis added). Consequently, to the extent Plaintiffs' design defect claim is based on Cialis's formulation, it is preempted. *See Yates v. Ortho-McNeil Pharm., Inc.*, 808 F.3d 281, 296–300 (6th Cir. 2015) ("[T]o the extent Yates argues that defendants should have altered the formulation of ORTHO EVRA® after the FDA had approved the patch, we find this claim clearly preempted.") Accordingly, all that remains of Plaintiffs' defective design claim is a claim sounding in defective *labeling*.

C. Defective Labeling under the WPLA

Defendant now seeks summary judgment on the remainder of Plaintiffs' WPLA claim for defective labeling, arguing that, without any evidence supporting proximate cause, the claim fails as a matter of law. (*See* Dkt. No. 86 at 6–18.)[2]

Under Washington law, "[i]n a products liability suit alleging inadequate warnings, the plaintiff must show that his or her injury was *proximately caused* by a product that was not

[1] Moderate changes must be reported to the FDA "at least 30 days *prior to* distribution of the drug product made using the change." *Id.* § 314.70(c) (emphasis added). Minor changes need only be reported in an annual report to the FDA. *Id.* § 314.70(d)(3). Major changes require FDA's "approval prior to distribution of the product made using the change." Id. § 314.70(b).

[2] Defendant also argues that Plaintiffs' design defect claim is barred under comment k to section 402A of the Restatement (Second) of Torts. (*Id.* at 14–15.) But that is not so. By the comment's express terms, proper preparation, marketing, and warnings are *prerequisites* to a manufacturer being able to qualify for immunity from strict liability. *See Taylor v. Intuitive Surgical, Inc.*, 389 P.3d 517, 528 (2017).

reasonably safe because adequate warnings or instructions were not provided." *Ayers By & Through Ayers v. Johnson & Johnson Baby Prod. Co., a Subsidiary of Johnson & Johnson Co.*, 818 P.2d 1337, 1339 (1991) (emphasis added) (citations omitted). To establish proximate causation, the plaintiff must show both cause in fact and legal causation. *Id.* (citation omitted). "Cause in fact refers to the actual connection between the act and an injury—but for the act, the injury would not have occurred." *Sherman v. Pfizer, Inc.*, 8 Wash. App.2d 686, 687 (2019). A warnings-based design defect claim requires proof that a different warning would have caused a different outcome. *See Rodman v. Ethicon, Inc.*, 2021 WL 2434521, slip op. at 5 (W.D. Wash. 2021) (proximate cause requires proof that a different warning would have "avoided the harm.").

According to Plaintiffs, the Cialis dose at issue was, in fact, prescribed by Dr. Bardin. (Dkt. Nos. 60-5 at 6–7, 60-7 at 8.) And Dr. Bardin testified that (a) he was aware of Cialis's risk of hemorrhagic strokes and (b) even if he had received a stronger warning of the risk(s), such as the one which Plaintiffs later suggest is adequate, Dr. Bardin would not have "changed [his] decision to prescribe Cialis [to Mr. Dearinger]." (Dkt. Nos. 60-1 at 17, 26, 27, 60-7 at 15.) Plaintiffs fail to provide any evidence rebutting this testimony.

Accordingly, the Court finds that Plaintiffs fail to establish a genuine issue of fact on the issue of proximate cause. And without this, Plaintiffs cannot proceed to trial on these claims. Accordingly, summary judgment is GRANTED.

D. Loss of Consortium

As Plaintiffs' predicate causes of action are dismissed, their loss-of-consortium claim *a fortiori* fails, because such claims cannot independently stand. *See Carter v. Ethicon Inc.*, 2021 WL 1893749, slip op. at 3 (W.D. Wash. 2021) (dismissing loss-of-consortium claim because all of plaintiff's statutory claims were dismissed).

Accordingly, Plaintiffs' loss of consortium claim is DISMISSED.

E. Motion for Reconsideration

Plaintiffs' motion for reconsideration (Dkt. No. 87) is premised on a *new* factual allegation that Dr. Horst was "the actual prescriber" of the Cialis, not Dr. Bardin. (*Id*. at 2–7.) But this flies in the face of Plaintiffs' earlier sworn testimony to the contrary. (Dkt. Nos. 60-5 at 6–7, 60-7 at 8) (stating that Dr. Bardin prescribed the Cialis). "A party cannot create an issue of fact by an affidavit contradicting his prior deposition testimony." *Kennedy v. Allied Mut. Ins. Co.*, 952 F.2d 262, 266 (9th Cir. 1991). Accordingly, the Court will not permit contradictory testimony from creating an issue of fact sufficient to survive summary judgment. *Russell v. Pac. Motor Trucking Co*., 672 F. App'x 629, 630 (9th Cir. 2016) ("The district court did not abuse its discretion in disregarding those portions of the affidavit that directly contradicted [plaintiff's] former deposition testimony.")

Plaintiffs' motion for reconsideration (Dkt. No. 87) is therefore DENIED.

III. CONCLUSION

For the foregoing reasons, Defendant's motion for summary judgment (Dkt. No. 86) is GRANTED and Plaintiffs' motion for reconsideration (Dkt. No. 87) is DENIED. The Court DISMISSES Plaintiffs' complaint (Dkt. No. 37) with prejudice.

DATED this 5th day of February 2024.

John C. Coughenour
UNITED STATES DISTRICT JUDGE